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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,903	01/11/2002	David Michael Goldstein	R0038G-DIV	4961

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,903

Applicant(s)

GOLDSTEIN ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-16, 22-31, 33, 38-40, 42, 43 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-16, 22-24, 33 and 38-40 is/are rejected.
- 7) ☒ Claim(s) 25-31, 42, 43 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claims 2-16, 22-31, 33, 38-40, 42, 43 and 45 are pending in the application.

Rejections made in the previous Office Action which do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

Specification

The amendment filed July 14, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- a) the amendment to page 5, line 3 (“cycloalkylalkenyl”); and
- b) the amendment to page 22, line 24 (“cycloalkylalkenyl”).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-15, 33 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support in the specification or the originally filed claims can be found for the R³ variable representing a cycloalkylalkenyl group (see claims 2 and 33). In the "Remarks" section of the Amendment filed July 14, 2004, Applicants state that the change to the claims was made to correct typographical errors. However, Applicants did not state where in the specification (page number and line number) or the original filed claims support could be found for the amendment. Applicants should specifically point out the support for any amendments. See M.P.E.P. §§ 714.02 and 2163.06.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-6, 16, 22-24, 33 and 38-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-21 of U.S. Patent No. 6,376,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims in the patent differ only by generic description of the pyrazole product used in the method.

See, for example, the patent's claim 19 wherein R^1 is hydrogen, R^2 is hydrogen, A and B are each aryl, R^3 is heteroalkoxy, R^4 , R^5 and R^6 are each hydrogen. One skilled in the art would thus be motivated to prepare pyrazole products embraced by the patent to arrive at the pyrazole products found in the instant claims with the expectation that

the obtained pyrazole products would be useful in treating inflammatory disorders such as arthritis. Therefore, the instant claimed method of using the pyrazole products would have been suggested to one skilled in the art.

Response to Arguments

Applicants' arguments filed July 14, 2004 have been fully considered. Applicants state that their previous offer to file a terminal disclaimer when all outstanding issues were resolved was made in error. Applicants argue that the instant application is a division of US 6,376,527 and therefore has the same priority and expiration dates. Applicants also argue that the instant application was filed prior to the issuance of US 6,376,527. Applicants also argue that claim 16 has been amended and therefore, claim 16 should be allowable.

In response, US 6,376,527 was not applied against the claims under 35 U.S.C. § 103. However, the rejection of the claims, including claim 16, under obviousness-type double patenting is proper since, as

stated above, there is an overlap of the claimed subject matter in the patent and in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-7, 12, 33 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faraci et al. {WO 94/13643}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim a method of treating a disease in a mammal treatable by administration of a p38 MAP kinase inhibitor (such as inflammation disorders) by administering pyrazole products.

Faraci et al. teach pharmaceutically active pyrazole products, that are structurally similar to the instant pyrazole products, that are administered in the instant claimed method. See in Faraci et al. (pages 1 and 2), for example, wherein A is $-C(=O)$, R_1 is amino, R_2 is alkyl, R_3 is phenyl substituted with hydroxy-alkyl and R_4 is phenyl. Also see, for example, the products on page 31, lines 5 and 12; page 39, line 11; and page 44, lines 12-14. Faraci et al. teach the pyrazole products are useful in treating disorders such as inflammatory disorders and immune suppression (page 5, lines 1-12).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the teaching in the prior art and the invention instantly claimed is that of generic description of the pyrazole products being administered for the intended use.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The motivation to make the pyrazole products derives from the expectation that structurally similar compounds would possess similar activity (e.g., an anti-inflammatory).

One skilled in the art would thus be motivated to prepare pyrazole products embraced by Faraci et al. to arrive at the pyrazole products found in the instant claims with the expectation that the obtained pyrazole products would be useful in treating inflammatory disorders such as arthritis. Applicants have not provided persuasive factual support in a side-by-side showing that the compounds used in the instant method of use show unexpected, beneficial and superior results over the compounds taught in Faraci et al. Therefore, absent such showing in a 1.132 Declaration, the instant claimed method of using the pyrazole products would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicants' arguments filed July 14, 2004 have been fully considered. Applicants argue that the table of results, found in the Remarks section of the Response filed July 14, 2004, shows unexpected results from the teachings in Faraci et al.

In response, Applicants' showing is unpersuasive since: (1) the results were not properly submitted in a 1.132 Declaration; and (2) it is not clear which compound(s) of Faraci et al. were compared. Therefore, the rejection of the claims under 35 U.S.C. § 103 is maintained.

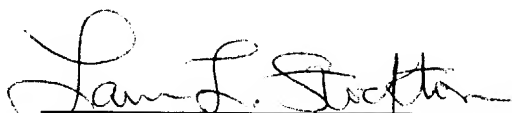
Allowable Subject Matter

Claims 25-31, 42, 43 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in cursive script, reading "Laura L. Stockton", written in black ink.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

September 20, 2004